

# Notice of Allowability

## Application No.

09/644,498

## Applicant(s)

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HELINA

## Examiner

Christopher J Nichols, Ph.D.

## Art Unit

1647

### -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 13 October 2004.
2. ☒ The allowed claim(s) is/are 65-89.
3. ☒ The drawings filed on 23 August 2003 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

## Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_\_
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

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### DETAILED ACTION

#### *Status of Application, Amendments, and/or Claims*

1. In view of the Appeal Brief filed on 13 October 2004, PROSECUTION IS HEREBY REOPENED, to allow entry of the Examiner's Amendment set forth below.
2. To expedite prosecution pursuant to MPEP §707, all Rejections and Objections are *withdrawn* and/or *moot* in view of Applicant's amendments.

### EXAMINER'S AMENDMENT

3. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.
4. In the Claims:

Claims 1-64 (Cancelled)

Claim 65 (Currently Amended) An in vitro method to produce a population that includes neurons and/or oligodendrocytes, the method comprising:

- (a) obtaining and/or isolating a mammalian neural stem cell; preparing an in vitro cell culture consisting essentially of astrocytes derived from a human neural stem cell;
- (b) culturing said neural stem cell to produce an in vitro cell culture that includes astrocytes;

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(c) dissociating and plating the in vitro cell culture; and

(e) (d) maintaining the in vitro cell culture in medium essentially free of serum comprising bFGF for at least one day,

to produce a population of cells that include neurons and/or oligodendrocytes.

Claim 66 (Currently Amended) The method of claim 65, further comprising, before step (b), maintaining the in vitro cell culture in the presence of bFGF.

Claim 67 (Currently Amended) The method of claim 65, wherein step (c) maintaining the in vitro cell culture in medium comprising bFGF, is performed for at least 10 days.

Claim 68 (Currently Amended) The method of claim 65, wherein step (c) maintaining the in vitro cell culture in medium comprising bFGF for at least one day further comprises mechanically disrupting cell clusters.

Claim 69 (Currently Amended) The method of claim 65, further comprising, after step (c), maintaining the in vitro cell culture in a medium in the absence of bFGF.

Claim 70 (Previously Presented) The method of claim 69 wherein the medium comprises DMEM.

Claim 71 (Previously Presented) The method of claim 69 wherein the medium comprises F12.

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Claim 72 (Previously Presented) The method of claim 69 wherein the medium comprises FGF-8.

Claim 73 (Previously Presented) The method of claim 69 wherein the medium comprises a member of the group consisting of retinoic acid, dbcAMP, BDNF, and GDNF.

Claim 74 (Previously Presented) The method of claim 65, wherein the cells are plated onto a substrate that comprises a member of the group consisting of poly L-lysine, polyornithine, and extracellular matrix.

Claim 75 (Previously Presented) The method of claim 65, wherein the concentration of the bFGF is in the range of 0.05 to 1000 ng per ml.

Claim 76 (Previously Presented) The method of claim 65, wherein heparin is present with the bFGF.

Claim 77 (Currently Amended) ~~The method of claim 65, wherein said method is used as a control step to identify other compounds that may exert a similar transdifferentiation effect on the astrocytes~~ An in vitro method to screen a compound for transdifferentiation activity, the method comprising:

(a) obtaining and/or isolating a mammalian neural stem cell;

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(b) culturing said neural stem cell to produce an in vitro cell culture that includes astrocytes;

(c) dissociating and plating the in vitro cell culture; and

(d) maintaining the in vitro cell culture in medium essentially free of

serum comprising a compound for at least one day,

and performing, as a control, steps comprising:

(a) obtaining and/or isolating a mammalian neural stem cell;

(b) culturing said neural stem cell to produce an in vitro cell culture that includes astrocytes;

(c) dissociating and plating the in vitro cell culture; and

(d) maintaining the in vitro cell culture in medium essentially free of

serum comprising bFGF for at least one day,

to produce a population of cells that include neurons and/or oligodendrocytes.

Claim 78 (Currently Amended) The method of claim 77, further comprising, before step (b), maintaining the in vitro cell culture in the presence of bFGF.

Claim 79 (Currently Amended) The method of claim 77, wherein step (c) maintaining the in vitro cell culture in medium comprising bFGF, is performed for at least 10 days.

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Claim 80 (Currently Amended) The method of claim 77, wherein step (c) maintaining the in vitro cell culture in medium comprising bFGF for at least one day further comprises mechanically disrupting cell clusters.

Claim 81 (Currently Amended) The method of claim 77, further comprising, after step (c), maintaining the in vitro cell culture in a medium in the absence of bFGF.

Claim 82 (Previously Presented) The method of claim 77 wherein the medium comprises DMEM.

Claim 83 (Previously Presented) The method of claim 77 wherein the medium comprises F12.

Claim 84 (Previously Presented) The method of claim 77 wherein the medium comprises FGF-8.

Claim 85 (Previously Presented) The method of claim 77 wherein the medium comprises a member of the group consisting of retinoic acid, dbcAMP, BDNF, and GDNF.

Claim 86 (Previously Presented) The method of claim 85, wherein the cells are plated onto a substrate that comprises a member of the group consisting of poly L-lysine, polyornithine, and extracellular matrix.

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Claim 87 (Previously Presented) The method of claim 77, wherein the concentration of the bFGF is in the range of 0.05 to 1000 ng per ml.

Claim 88 (Previously Presented) The method of claim 77, wherein heparin is present with the bFGF.

Claim 89 (Previously Presented) The method of claim 77 wherein the compound comprises at least one neurotrophin.

5. Authorization for this examiner's amendment was given in a telephone interview with Curtis Herbert on 13 December 2004.

### *Summary*

6. Claims **65-89** are hereby allowed.

7. The Examiner acknowledges that acceptance of the above Examiner's Amendment does not mitigate in any way, shape, or form, Applicant's right to pursue additional subject matter in continuation, continuation-in-part, and/or divisional applications pursuant to 35 U.S.C. §120 and §121.

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***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Christopher James Nichols, Ph.D.** whose telephone number is **(571) 272-0889**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Brenda Brumback** can be reached on **(571) 272-0961**.

The fax number for the organization where this application or proceeding is assigned is **703-872-9306**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

CJN

December 13, 2004

*Elizabeth C. Kemmerer*

ELIZABETH KEMMERER  
PRIMARY EXAMINER